

REMARKS

Reconsideration of the application and allowance of all pending claims are respectfully requested in light of the remarks below.

Pursuant to 37 C.F.R. §1.121(c)(1)(ii), since claims 101 and 104 have been amended, a mark-up version of these claims showing all the changes relative to the previous version of the claims is provided and attached hereto.

In the Office action, the Examiner continues to assert that Applicants have not fully disclosed the prior art as required by the previous office action (paper no. 32, page 7, lines 3-12). Specifically, the Examiner stated that no publication or carefully drawn sketch with meaningful legends and explanations has been given and no disclosure of what processes and what fluids have been processed in the prior art has been provided. More specifically, in the previous Office action, the Examiner requested further disclosure of the prior art discussed in the Description of Prior Art section of the specification of the above-identified application.

Applicants respectfully submit that the first two paragraphs in the Description of Prior Art section on page 2 of the specification of the present invention refer to this 1992 Genentech device. See Second Declaration of Richard Wisniewski, 8, submitted herewith. The first Declaration of Richard Wisniewski and its exhibits, submitted with the Supplemental Response on January 24, 2002, clearly show and explain how the 1992 Genentech device operates. As Applicants have repeatedly stated, no thermal bridge is formed by the medium in the gap between the fin tips and the interior wall of the 1992 Genentech device. Id.

Applicants also submit that the prior art described in the third paragraph of this section refers to a device having ribs welded to both the core and the interior wall of the vessel. See Second Declaration of Richard Wisniewski, 9, submitted herewith. Since the ribs were connected to both the internal core and the interior wall of the vessel, no thermal bridge can be formed by the medium between a fin tip and the interior wall of the vessel. Id. Heat transfer occurs only through the external wall of the vessel. Such vessels can be used in heat storage devices for, e.g., paraffin. Id. Although not relevant to the particular freezing of biopharmaceutical materials, an example of such vessels in which the ribs are connected to the

core and the interior wall is found in U.S. Patent Nos. 2,441,376 to Stiening and 2,129,572 to Finnegan.

During a recent telephone conversation with the Examiner, the Examiner mentioned that he wanted to know more information concerning the distance between the fins and the interior wall of the 1992 Genentech container. However, Applicants respectfully submit and reiterate that all information in their possession and knowledge concerning the 1992 Genentech container has been disclosed to the U.S. Patent Office. As proof thereof, Applicants respectfully submit the Second Declaration of Richard Wisniewski, which confirms that the information concerning the Genentech device and the prior art mentioned in the specification of the present application has been disclosed to the U.S. Patent Office. See Second Declaration of Richard Wisniewski, 7-8, submitted herewith. Although he does not remember the exact distance between the fin tip and the interior wall of the 1992 Genentech device, Mr. Wisniewski does state in this second declaration that there was a large gap between the fin tips and the interior wall of the 1992 Genentech vessel (e.g. greater than 4 inches). Id. Moreover, Mr. Wisniewski offers his reasons in designing the small, thin fins in the 1992 Genentech device. Id.

In the Office action, the Examiner suggests that documents illustrating the prior art discussed in the specification were shown to SPE Lazarus and either Examiner Chandler or Examiner Pryor at some prior interview in this application or one of the two other filed at or near the filing date of this application. Other than the presentation document entitled "Proceedings of the International Congress: Advanced Technologies For Manufacturing Of Aseptic & Terminally Sterilized Pharmaceuticals & Biopharmaceuticals" for a convention held in February 1992 (which was already disclosed to the US PTO on January 24, 2002, attached as Exhibit A to the first Declaration of Richard Wisniewski and contained the 1992 Wisniewski and Wu publication, which included the drawing of the 1992 Genentech device) was the document Applicant brought to a prior interview. Applicants respectfully submit that they cannot recall any other documents or prior art being shown to any Examiner previously. Accordingly, Applicants cannot determine any other documents or applications the Examiner is basing his understanding on. In fact, this convention presentation document contained.

In the present Office action, the Examiner has also requested an election of species. Applicant respectfully responds to the election requirement in the outstanding Office action as follows:

I. The Examiner's Election Requirement

The Examiner has also noted that this application contains claims directed to the following patentably distinct species of the claimed invention:

- First species: Figures 1 and 2
- Second species: Figure 4
- Third species: Figure 5
- Fourth species: Figure 6
- Fifth species: Figure 7
- Sixth species: Figure 8
- Seventh species: Figure 9, (more than one, maybe)
- Eighth species: Figure 10
- Ninth species: Figures 11 and 12
- Tenth species: Figure 13
- Eleventh species: Figure 14; and
- Twelfth species: Figure 15 and an in-determinant number of additional species illustrated in Figures 16-19

II. Applicant's Election of Invention and Species

Applicants provisionally elect to pursue the species corresponding to the First Species (Figures 1 and 2), and respectfully submit that claims 88-89, 96, 101, 105-116, and 118-119 read on the species of Figures 1 and 2. Applicants respectfully submit that all of these claims are generic to the first, third, fourth, fifth, sixth, and seventh species and respectfully submit that upon allowance of the generic claims, Applicants are entitled to consideration of claims to the additional species which are written in dependent form or otherwise include all the limitations of the allowed generic claim.

IV. Applicants' Traversal

Applicants respectfully submit that the invention is directed to a method and apparatus for processing a biopharmaceutical product. Applicants respectfully submit that (1) all groups of claims are properly presented in the same application; (2) undue diverse searching should not be required; and (3) all claims should be examined together. Applicants respectfully traverse the


requirement for restriction and election on the grounds that searching all of the embodiments of the invention would not be unduly burdensome and, in fact, would be necessary to ensure a complete search for a proper examination on the merits of any one of the identified species. It is further submitted that in order to provide a complete and exhaustive search of any of the species as grouped in the Office Action, the search should include the search directed to each of the other species as grouped in the Office Action. Furthermore, since the method claims mirror the apparatus claims, it would not be unduly burdensome to include all of the claims in the same application.

Conclusion

For the foregoing reasons, it is respectfully submitted that the election requirement should be withdrawn and an action on the merits of all of the claims is respectfully solicited. If any issues exist, or if the Examiner has any suggestions for expediting allowance of the application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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MARKED-UP VERSION OF THE CLAIMS

In the Claims:

Please cancel claim 117 and amend claims 101 and 104 as follows:

101. (Amended) The method of claim [80] 88, further comprising:

positioning baffles within the fluid flow path between the jacket and the exterior wall of said vessel to define a spiraling path for fluid.

104. (Amended) The method of claim [83] 103, further comprising:

forming a thermal bridge by said medium between said one or more heat transfer members of said interior wall and said one or more heat transfer members of said heat exchange structure wherein heat is transferred from said heat transfer member of said heat exchange structure through said thermal bridge to said heat transfer member of said interior wall when said interior wall is actively cooled.